REMARKS/ARGUMENTS

Claims 1-31 are pending in the application. Claims 32-61 are added by way of this Amendment. Claims 4, 27-31 have been withdrawn without prejudice. Claims 1, 17, 21, and 22 have been amended. The following discussion will focus on the independent claims of the application, claims 1, 17, 22, 32, 36, 52, and 58.

Claims 1-14 and claims 16-31 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over the OSHA Irritant Smoke Protocol ("OSHA"), in view of U.S. Patent No. 5,073,347 to Garren ("Garren"). Claim 15 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over OSHA in view of U.S. Patent No. 3,938,392 to Rodrigues ("Rodrigues"). Applicant respectfully traverses these rejections.

Additionally, the Examiner has objected to the formal drawings because the numerals are indistinct. These objections have been addressed by separate letter to the official draftperson. Further, the Examiner has objected to the disclosure because of an inconsistency with the drawings. Applicant has amended the specification to conform with the drawings and submits herewith a substitute page of the specification, reflecting the amendment. Accordingly, withdrawal of these objections is respectfully requested.

Applicant acknowledges the interview with the Examiner that took place on October 24, 2002 and thanks the Examiner for his participation and helpful suggestions in the interview.

I. Claim Rejections – 35 U.S.C. § 103(a)

Amended claim 1 now recites an apparatus for testing equipment located in a local environment by presenting a detectable indicator gas therein, the apparatus comprising a container portion, a chemical substance stored in said container portion, a pump integrally formed as one piece with said container portion and is joined seamlessly with said container portion, and an outlet.

While OSHA does disclose a testing apparatus, it does not teach an apparatus that has a pump portion joined seamlessly with a container portion. Indeed, the OSHA procedures described in the reference call for the use of two **separate** components – a smoke tube and a

pump. Specifically, the OSHA procedures require a method breaking both ends of a "ventilation smoke tube" **and attaching** one end of the smoke tube to a "low flow air pump" or an "aspirator squeeze bulb." OSHA, p. 227.

Further, Garren does not cure the deficiencies of OSHA. Garren is directed to a unitary volumetric pipette for dispensing liquids, formed by joining two components. *See* Garren, col. 1, lns. 8-13. In contrast to the subject matter of the claimed invention, Garren is primarily concerned with creating a volumetric pipette that eliminates some of the problems associated with disposable plastic pipettes, such as inaccuracy, by manufacturing the pipette in two components, a bulb portion and a stem portion, which are then bonded together by heat bonding or adhesive bonding. *See* Garren, col. 5, lns. 31-45; col. 10, lns. 8-10. By bonding the two components together, the device in the Garren reference inherently has a seam between the bulb portion and the stem portion. This is in contrast to the present invention, as claimed in amended claim 1, where the container portion is joined seamlessly with the pump.

To establish *prima facie* obviousness, the Examiner must establish that all claim limitations are taught or suggested by the prior art. *In re Roy,* 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). Thus, even if Garren could be properly combined with OSHA (this point is discussed below), the resulting combination does not establish obviousness because the combination does not include all of the elements discussed above (which are recited in amended claim 1).

Independent claims 17 and 22, as amended, also include the limitation that the pump portion and container portion are joined seamlessly. For the reasons discussed with respect to claim 1, independent claims 17 and 22 as amended are also nonobvious over the combination of Garren and OSHA. Claims 2,3,5-16, 18-21, and 22-26 are dependent from independent claims 1, 17, and 22, respectively and contain additional patentable features. These dependent claims are patentable for the reasons discussed above with respect to independent claims 1, 17, and 22.

Even if all elements of claim 1 were available from the Garren and OSHA references, there is no teaching in the cited references, or from the general knowledge available to one of ordinary skill in the art, which would suggest or motivate the combination of the teachings of

these two references. Such a combination of prior art teachings cannot be shown to establish obviousness absent some teaching, incentive, or suggestion in the prior art. *ACS Hosp. Sys., Inc. v. Montefiore Hosp.,* 732 F.2d 1572, 1577, 2221 U.S.P.Q. 929, 933 (Fed. Cir. 1984); *In Re Fine,* 837 F.2d 1071, 35 U.S.P.Q. 1596 (Fed. Cir. 1988). For example, the present invention solves a problem that was not even identified in the art. Previously, as disclosed in OSHA, fit testing required a glass tube, which was broken at both ends, and a pump, which was attached to one of the ends of the tube. The tube component was completely separate from the pump component until just before the test was performed. This required the pump, often in the form of a squeeze bulb, to be transported with the tubes, and not lost during the multiple uses of the squeeze bulbs. It is important to note that the squeeze bulbs used in this art are a special kind of squeeze bulb, manufactured expressly for this purpose and must be specially ordered, because they must dispense a precise volume of air, according to OSHA standards. Thus, keeping up with the squeeze bulbs is crucial to performing multiple testing procedures. If a bulb is lost, it is not a simple matter of picking up a replacement at the local drugstore.

Until the present invention, no one in the art had even thought of creating an integrally formed tube-and-pump apparatus because of the different properties that each component required. That is, the pump or squeeze bulb must be formed from a flexible material that can be squeezed, while the tube portion must be formed from a material that is sufficiently impermeable so as to protect the chemical in the container portion from reacting with the surrounding environment until the test is ready to be performed. These two necessary properties, flexibility and impermeability, are not usually found in one material, and so the general perception in the art **taught away** from the present invention. That is, the general perception taught that two separate components must be used – a pump and a container – and attached just prior to performing the test.

The present invention overcomes these problems and provides additional benefits as described more fully in the specification. Further, only now that applicants have disclosed the present invention has this problem been identified in the art, and thus and to suggest combining Garren with OSHA is using impermissible hindsight.

Accordingly, the combination of Garren and OSHA does not provide a proper basis for a rejection under 35 U.S.C. § 103(a). Withdrawal of the Examiner's rejection of claims 1-31 under 35 U.S.C. § 103(a) is respectfully requested.

Further, new claims 32-61 are patentable over Garren and OSHA. New claim 32 is directed to a method of manufacturing a testing apparatus, including the step of integrally forming a container portion and a squeeze bulb portion using a flexible material and applying a second material adjacent the flexible material to form a laminate therewith such that the second material reduces the permeability of the flexible material. New independent claims 36, 52, and 58 also include similar limitations regarding the formation of a laminate. While Garren suggests bonding two components together (a bulb portion and a stem portion), Garren does not suggest forming a testing apparatus using two material layers distinct from each other and applying the second material adjacent the first material to form a multi-layer laminate, as required new independent claims 32, 36, 52, and 58. In fact, Garren is not directed to a testing apparatus or using a multi-layer laminate with a pipette. OSHA likewise does not address a smoke tube apparatus formed using a multi-layer laminate. Thus, even assuming Garren could be properly combined with OSHA (this point is discussed above), the resulting combination does not establish obviousness because the combination does not include all of the elements discussed above, which are recited in new claims 32-60.

Accordingly, new claims 32-60 are patentable for the reasons discussed above.

Attached hereto is a version of the pending claims marked up, captioned **"Version With Markings To Show Changes Made."** Also attached is a clean version of the claims pending in the application, after the current amendment, captioned **"Clean Version of Pending Claims."**

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

If the appropriate Petition for an Extension of Time is not attached hereto (or any other Petition required of the application), this statement shall serve as Applicants' Petition to

the U.S.P.T.O. Please charge any fees that are due for any Petition or any fee required of this filing to the deposit account of Fulbright & Jaworski L.L.P., Account No. 06-2375 under Order No. P02054US1 (10024546).

The undersigned is available for consultation at any time, if the Examiner believes such consultation may expedite the resolution of any issues.

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Respectfully submitted,

By 

Jayne C. Piana
Registration No.: 48,424
FULBRIGHT & JAWORSKI L.L.P.
1301 McKinney, Suite 5100
Houston, Texas 77010-3095
(713) 651-5151
(713) 651-5246 (Fax)
Attorneys for Applicant

Version With Markings to Show Changes Made

In the Specification

Please replace the last paragraph on page 3 with the following paragraph.

FIG. 2 is a cross-sectional view of the testing apparatus in FIG. 1 taken along the line 2-2.

In the Claims

1. (Amended) An apparatus for testing equipment located in a local environment by presenting a detectable indicator gas therein, said apparatus comprising:

a container portion;

a chemical substance stored in said container portion;

a pump operable to draw air into said container and in contact with said chemical substance to generate a detectable indicator gas, wherein said pump is integrally formed as one piece and wherein said pump is joined seamlessly with said container portion; and

an outlet to said container for directing said indicator gas into the local environment.

Please cancel claim 4 without prejudice.

17. (Amended) A method of manufacturing an apparatus for testing equipment in a local environment by presenting a detectable indicator gas therein, said method comprising the steps of:

providing a flexible material;

integrally forming, as one piece, a container portion and a squeeze bulb portion using the flexible material whereby the container portion and the bulb portion are seamlessly joined; and

storing a chemical substance in the container portion such that, upon operation of the bulb to draw air into the container portion, a detectable indicator gas is generated for presentation into the local environment.

21. (Amended) The method of claim 17, further comprising the step[s] of providing a second material distinct from the [plastic] flexible material, whereby said integrally forming step includes forming [said] the container portion and [said pump] the squeeze bulb portion from a laminate comprising said [plastic] flexible material and said second material.

22. (Amended) A method of testing equipment in a local environment by presenting a detectable indicator gas therein, said method comprising the steps of:

storing a chemical substance, reactive with air to produce an indicator gas, in a container formed substantially from a polymeric material;

providing a polymeric squeeze bulb device in operative communication with the container, and formed integrally, as one piece, and seamlessly joined, therewith;

breaking a portion of the container tube to provide an outlet;

operating the squeeze bulb to draw air past the chemical substance to produce a human detectable indicator gas;

directing the indicator gas outward of the container and into the local environment; and

detecting the indicator to determine the operability of the equipment in the local environment.

Version With Currently Pending Claims

1. (Amended) An apparatus for testing equipment located in a local environment by presenting a detectable indicator gas therein, said apparatus comprising:

a container portion;

a chemical substance stored in said container portion;

a pump operable to draw air into said container and in contact with said chemical substance to generate a detectable indicator gas, wherein said pump is integrally formed as one piece and wherein said pump is joined seamlessly with said container portion; and

an outlet to said container for directing said indicator gas into the local environment.

2. The testing apparatus of claim 1, wherein said pump is a manually squeezable bulb.

3. The testing apparatus of claim 1, wherein said pump is selected from the group of manually operable pumps consisting of: a manually squeezable bulb, a bellows-driven pump, a syringe, and combinations thereof.

5. The testing apparatus of claim 1, wherein said container portion and said pump are formed from a plastic material.

6. The testing apparatus of claim 5, wherein said plastic material is low density polyethylene.

7. The testing apparatus of claim 1, wherein said container portion is formed from a first material and said pump is formed from a second material distinct from said first material.

8. The testing apparatus of claim 1, wherein said container portion and said pump are formed from a laminate of at least a first material layer and a second material layer distinct from said first material layer.

9. The testing apparatus of claim 1, wherein said container portion and said pump form a substantially permanent molded structure.

10. The testing apparatus of claim 1, wherein said chemical substance is reactive with the container environment, upon operation of the pump, to generate said indicator gas.

11. The testing apparatus of claim 1, wherein said chemical substance is selected such that said chemical substance and air drawn into said container portion generate a scented indicator gas upon contact.

12. The testing apparatus of claim 1, wherein said chemical substance is reactive with air to produce an irritant gas.

13. The testing apparatus of claim 12, wherein said chemical substance is liquid $SnCl_4$ and said indicator gas is an acid vapor fume.

14. The testing apparatus of claim 1, wherein said chemical substance is reactive with the container environment, upon operation of the pump, to generate a visually detectable indicator gas.

15. The testing apparatus of claim 1, wherein said pump has a hole to allow finger release of pressure.

16. The testing apparatus of claim 1, further comprising an exterior layer of laminate that seals the container.

17. (Amended) A method of manufacturing an apparatus for testing equipment in a local environment by presenting a detectable indicator gas therein, said method comprising the steps of:

providing a flexible material;

integrally forming, as one piece, a container portion and a squeeze bulb portion using the flexible material whereby the container portion and the bulb portion are seamlessly joined; and

storing a chemical substance in the container portion such that, upon operation of the bulb to draw air into the container portion, a detectable indicator gas is generated for presentation into the local environment.

18. The method of claim 17, wherein the flexible material is plastic.

19. The method of claim 17, further comprising the step of sealing a breakable end tip of the container tube portion located opposite the squeeze bulb.

20. The method of claim 17, wherein the step of storing includes storing a chemical that, when contacted by air drawn into the container portion generates a visually detectable indicator gas.

21. (Amended) The method of claim 17, further comprising the step of providing a second material distinct from the flexible material, whereby said integrally forming step includes forming the container portion and the squeeze bulb portion from a laminate comprising said flexible material and said second material.

22. (Amended) A method of testing equipment in a local environment by presenting a detectable indicator gas therein, said method comprising the steps of:

storing a chemical substance, reactive with air to produce an indicator gas, in a container formed substantially from a polymeric material;

providing a polymeric squeeze bulb device in operative communication with the container, and formed integrally, as one piece, and seamlessly joined, therewith;

breaking a portion of the container tube to provide an outlet;

operating the squeeze bulb to draw air past the chemical substance to produce a human detectable indicator gas;

directing the indicator gas outward of the container and into the local environment; and

detecting the indicator to determine the operability of the equipment in the local environment.

23. The method of claim 22, wherein the indicator gas is a visually observable gas, said detecting step including visually observing the behavior of the indicator gas in the local environment.

24. The method of claim 23, wherein said observing step includes visually observing the flow of the indicator gas in the local environment.

25. The method of claim 22, wherein the chemical substance is liquid $SnCl_4$ or H_2SO_4 and said step of operating the squeeze bulb generates a chemical reaction producing an irritant indicator gas.

26. The method of claim 22, wherein the indicator gas is indicator gas having a pre-selected scent, said observing step including detecting the scent of the indicator gas to determine the operability of the equipment.

32. (New) A method of manufacturing an apparatus for testing equipment in a local environment by presenting a detectable indicator gas therein, said method comprising the steps of:

providing a flexible material;

providing a second material;

integrally forming, as one piece, a container portion and a squeeze bulb portion using the flexible material and applying the second material adjacent the flexible material to form a laminate therewith such that the laminate is substantially less permeable than the flexible material; and

storing a chemical substance in the container portion such that upon operation of the bulb to draw air into the container portion, a detectable indicator gas is generated for presentation into the local environment.

33. (New) The method of claim 32, wherein said step of providing a flexible material includes providing a plastic material.

34. (New) The method of claim 32, further comprising the step of sealing a breakable end tip of the container tube portion located opposite the squeeze bulb.

35. (New) The method of claim 32, wherein the step of storing includes storing a chemical that, when contacted by air drawn into the container portion, generates a visually detectable indicator gas.

36. (New) An apparatus for testing equipment located in a local environment by presenting a detectable indicator gas therein, said apparatus comprising:

a container portion;

a chemical substance stored in said container portion;

a pump operable to draw air into said container and in contact with said chemical substance to generate a detectable indicator gas; and

an outlet to said container for directing said indicator gas into the local environment;

wherein said container portion and said pump are formed from a laminate of at least a first material layer and a second material layer distinct from said first material layer.

37. (New) The apparatus of claim 36, wherein said pump is a manually squeezable bulb.

38. (New) The apparatus of claim 36, wherein said pump is selected from the group of manually operable pumps consisting of: a manually squeezable bulb, a bellows-driven pump, a syringe, and combinations thereof.

39. (New) The apparatus of claim 36, wherein said pump is joined seamlessly with said container portion.

40. (New) The apparatus of claim 36, wherein said container portion and said pump are formed form a plastic material.

41. (New) The apparatus of claim 40, wherein said plastic material is low density polyethylene.

42. (New) The apparatus of claim 36, wherein said container portion and said pump form a substantially permanent molded structure.

43. (New) The apparatus of claim 36, wherein said chemical substance is reactive with the container environment, upon operation of the pump, to generate said indicator gas.

44. (New) The apparatus of claim 36, wherein said chemical substance is selected such that said chemical substance and air drawn into said container portion generate a scented indicator gas upon contact.

45. (New) The apparatus of claim 44, wherein said chemical substance is liquid $SnCl_4$ and said indicator gas is an acid vapor fume.

46. (New) The apparatus of claim 36, wherein said chemical substance is reactive with the container environment, upon operation of the pump, to generate a visually detectable indicator gas.

47. (New) The apparatus of claim 36, wherein said pump has a hole to allow finger release of pressure.

48. (New) The apparatus of claim 36, wherein said second material layer seals said container.

49. (New) The apparatus of claim 36, wherein said second material layer completely surrounds said testing apparatus.

50. (New) The apparatus of claim 49, wherein said second material layer is a mylar bag.

51. (New) The apparatus of claim 36, wherein said second material layer is sealably disposed about said pump and said container portion.

52. (New) A method of manufacturing an apparatus for testing equipment in a local environment by presenting a detectable indicator gas therein, said method comprising the steps of:

providing a first material having one or more physically advantageous properties;

providing a second material distinct from said first material and the second material having one or more physically advantageous properties;

integrally forming, as one piece, a container portion and a pump portion using the first material and applying the second material adjacent the first material to form a laminate therewith such that the apparatus is characterized by the physically advantageous properties of the first material and the second material; and

storing a chemical substance in the container portion such that, upon operation of the bulb to draw air into the container portion, a detectable indicator gas is generated for presentation into the local environment.

53. (New) The method of claim 52, wherein said step of providing a first material includes selecting one or more physically advantageous properties selected from the group of physically advantageous properties including: flexibility, durability, high strength, tear resistance, and combinations thereof.

54. (New) The method of claim 53, wherein said step of providing a second material includes selecting one or more physically advantageous properties selected from the group of physically advantageous properties including: low permeability, inertness, non-reactive with the chemical substance, and combinations thereof.

55. (New) The method of claim 52, wherein said step of storing includes storing a chemical that, when contacted by air drawn into the container portion, generates a visually detectable indicator gas.

56. (New) The method of claim 52, wherein said step of providing a first material includes providing a polymeric material.

57. (New) The method of claim 52, wherein said step of providing a second material includes providing a mylar material.

58. (New) A method of manufacturing an apparatus for testing equipment in a local environment by presenting a detectable indicator gas therein, said method comprising the steps of:

providing a testing device including the steps of:

providing a container portion,

storing a chemical substance in said container portion, and

using a polymeric material, integrally forming a squeeze bulb as one-piece with the container portion, such that the squeeze bulb is operable to draw air into the container portion to generate a reaction between the chemical substance and the air, and to produce a detectable indicator gas; and

surrounding the testing device with a packaging layer.

59. (New) The method of claim 58, wherein the packaging layer is a mylar material.

60. (New) The method of claim 58, wherein the polymeric material is low density polyethylene.

61. (New) The method of claim 60, wherein the packaging layer is substantially less permeable than the polymeric material, such that the step of surrounding the testing device substantially reduces the permeability of the testing device.